

**REMARKS**

Consideration and entry of this paper, and reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance, or in better condition for appeal.

**I. STATUS OF THE CLAIMS AND FORMAL MATTERS**

Attached hereto is a substitute specification as Exhibits A and B. Exhibit A is the substitute specification with markings to show all the changes relative to the immediate prior version. Exhibit B is a clean version of the substitute specification. No new matter has been introduced.

Claims 132-152 were pending in this application. Claims 132-152 have been cancelled. Claims 153-169 have been added. Support for claim 153 may be found throughout the application, including for example, in the attached substitute specification on: page 14, paragraphs 1 and 4, directed to insect cells that grow in serum-free media; page 14, paragraph 5 and page 15, paragraphs 1 and 2, directed to a method of using insect cells that grow in serum-free media to produce recombinant baculovirus and recombinant gene products; page 26, paragraph 4, directed to the use of a baculovirus expression system comprising a nucleic acid molecule (preferably encoding an expression product comprising an epitope or antigen) to infect insect cells that grow in serum-free media; and page 77, Example 12, directed to human erythropoietin produced in insect cells of the present invention. Support for claims 159-169 may be found throughout the application, including for example, on pages 2-4 of the substitute specification. No new matter has been introduced.

**Objections to the claims are overcome**

Claims 132-152 were objected to based on informalities. In the interest of expediting prosecution, claims 132-152 have been cancelled, rendering the objection moot.

**Double patenting rejection is overcome**

Claims 132 and 151-152 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-11 of U.S. Patent 6,103,526. Although Applicants do not agree with the Office Action, in the interest of

expediting prosecution, claims 132 and 151-152 have been cancelled. However, a Terminal Disclaimer as to U.S. Patent No. 6,103,526 is being filed concurrently herewith.

## II. THE 35 U.S.C. § 112 REJECTIONS ARE OVERCOME

Claims 133-138 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing the enablement requirement. According to the Office Action, there is no support for the recitation of *in vivo* activity. Claims 133-138 were also rejected for allegedly containing new matter. Claims 133-138 were also rejected for allegedly being indefinite. Although Applicants disagree with the Office Action, claims 133-138 have been cancelled.

## III. THE ART REJECTIONS ARE OVERCOME

Claims 132-138 and 151 were rejected under 35 U.S.C. § 103(a) as allegedly being anticipated by Quelle *et al.* (“Quelle”) in view of Dorland’s Illustrated Medical Dictionary (“Dorland’s”) and further in view of Inlow *et al.* (“Inlow”). Claims 139-150 were rejected under 35 U.S.C. § 103(a) as allegedly being anticipated by Quelle in view of Dorland’s and Inlow, and further in view of Morrison.

Although Applicants disagree with the Office Action, claim 132-151 have been cancelled. Applicants submit that the subject matter of the new claims are not rendered obvious over Quelle in view of Dorland’s and Inlow.

Quelle does not teach or suggest a recombinant EPO having *in vivo* activity, namely erythropoiesis, nor does Quelle teach or suggest culturing insect cells in serum-free media.

The Office Action indicates that erythropoiesis is an inherent activity of EPO and relies on Dorland’s to support this statement. Applicants agree that, indeed, erythropoiesis is an inherent activity of EPO. However, this point is moot, as the claimed invention is directed to ***recombinant*** EPO, and erythropoiesis is **NOT** an inherent activity of ***recombinant*** EPO.

The Office Action also indicates that it would be obvious in view of Inlow to grow insect cells of the present invention in serum-free media. Applicants respectfully disagree.

The Examiner is directed to the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowicz*, 27 U.S.P.Q. 2d 1063 (BPAI 1993). Although a teaching, suggestion, or motivation

to combine is no longer rigidly required for a finding of obviousness, it remains the primary guarantor against a non-statutory hindsight analysis. *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1365 (Fed. Cir. 2008). Further, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): “The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of the modification.” For the §103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicant’s disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed.Cir. 1988).

Furthermore, The Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: “[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.” *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727.

Applying the law to the instant facts, the references relied upon by the Office Action does not disclose, suggest or enable the Applicants’ invention. Quelle does not teach or suggest that growing insect cells in serum-free media would result in biologically active recombinant EPO. Further, Inlow does not teach or suggest the production of a substantially pure, recombinant, glycosylated EPO that has *in vivo* activity, including erythropoiesis.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.